UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,765	12/29/2003	Illana Gozes	019856-000210US	8714

20350 7590 04/29/2008

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
04/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,765	GOZES ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-15,17-22 and 26-28* is/are pending in the application.

4a) Of the above claim(s) *2-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10-15,17-22,26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's Response and Amendments filed 26 February 2008 are acknowledged and entered. Claims 1-8, 10-15, 17-22, and 26-28 are pending. Claims 9, 16, 23-25, and 29 have been cancelled by Applicant. Claims 2-8 are withdrawn, as being drawn to non-elected inventions. Claims 1, 10-15, 17-22, and 26-28 are under examination.

Response to Arguments/Amendments
Claim Objections/Rejections Maintained
Claim Rejections - 35 USC § 112, First Paragraph
Written Description

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 12, 13, 15, 17-19, and 22 **remain rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, are maintained for reasons of record and for the reasons set forth herein.

Applicant argues that an adequate description of the claimed invention is set forth in the specification such that it shows Applicants were in possession of the claimed genus at the time of filing. In support of their arguments, Applicant cites Enzo Biochem, Inc. v. Gen- Probe, Inc., 63 USPQ2d 1609 (Fed. Cir. 2002), for the proposition that an applicant may show that an invention is complete by a disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that Applicant was in possession of the claimed invention (Remarks, page 6, last paragraph). Applicant also argues the applicability of the Written Description Guidelines because a "description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces See, e.g., 66 Fed. Reg. 1099, 1106 (2001)" (Remarks, p. 7, second paragraph). Applicant also cites Falkner v. Inglis in support of the argument that the absence of working examples does not render written description inadequate and that actual reduction to practice is not required (Remarks, p. 7, second paragraph). Applicant argues that while claim 1 describes a large number of possible peptide sequences, a skilled artisan would recognize that each of the

sequences include a functional core ADNF III polypeptide and be able to add additional amino acids as described (Remarks, p. 7, third paragraph). Applicant argues that the specification provides examples within the scope of claim 5 (Remarks, p. 7, third paragraph). [The examiner notes that claim 5 is withdrawn and not presently under examination.] Applicant argues that paragraphs 62 and 63 disclose other sequences where the amino acids added to the core peptide comprise a membrane translocation domain, a peptide with additional functional qualities (Remarks, p. 7, third paragraph). Applicant argues that the specification sets forth the structure of the ADNF III core sequence (SEQ ID NO: 2) and the correlating function of treating MS (Remarks, p. 7, fourth paragraphs). Applicant's arguments have been fully considered, but they are not persuasive.

A review of the claim language indicates that the claims are drawn to a method for treating MS comprising administering a composition comprising a genus of ADNF III polypeptides with an active core site of NAVSPSIPQ (compare claim 1). It is important to note that the open language of the word "comprising" in claim 1, for example, places no limit on the number or form of amino acid residues that may be on either side of the core sequence of SEQ ID NO: 2 (NAVPSIPQ). Additionally, claims 15 and 22 recite polypeptides of the composition which may encompass up to 44 additional amino acids (about 20 on either side of the recited active core sequence). This translates into a minimum of 4.4×10^{20} possible polypeptide variants, considering only the standard 20 L-amino acids at each position with an unspecified residue. This number increases, when substituting one or more D-amino acids as set forth in claims 12 and 13, 18, and 19. Claims 17-22 are also drawn to the method of claim 1 wherein the composition further comprises a genus of ADNF I polypeptides comprising an active core site comprising SEQ ID NO: 1 (SALLRSIPA), which, in preferred embodiments, may encompass up to 44 additional amino acids. This translates into a minimum of 4.4×10^{20} possible polypeptides, considering only the standard 20 L-amino acids at each position with an unspecified residue. This number would increase if non-standard amino acids or D-amino acids were added, as they are in claims 18 and 19. Even if a polypeptide with an active core sequence of SEQ ID NOs: 1 or 2 would retain the function of the active core sequence, one of skill in the art would still not know anything about the structure of the claimed genus other than the core sequence of 8 or 9 amino acid residues. When viewed in light of the genus of functional polypeptides comprising 44 amino acid residues, the disclosed sequence of 8 or 9 residues, only amounts to 18% and 20% of the protein structure, respectively. A genus of polypeptides where only 18% to 20% of the structure is disclosed (meaning that 80% to 82% of the structure is completely unknown) does not have adequate written description.

The genus of ADNF III polypeptides and the genus of ADNF I polypeptides are highly variable in structure (as shown in the NCBI references recited in the Office Action of 6 July 2006). The structure which is asserted to make up the polypeptide **must be clearly and positively specified**. The structure must be organized and correlated in such a manner as to present a complete operative embodiment which is adequately described in the specification. The instant disclosure fails to provide an adequate description of a sufficient number of variant ADNF III and ADNF I polypeptides that function to treat MS. The general knowledge and level of those of ordinary skill **does not** supplement the omitted description because specific, not general, descriptions are needed. While "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included to "demonstrate that the patentee possessed the full scope of the [claimed] invention." Lizardtech v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005). As such, one of skill in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

Insofar as Applicant relies on Enzo Biochem, Inc. v. Gen-Probe, Inc., (Fed Cir. 2002), for the proposition that Applicant may show that an invention is complete by a disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that Applicant was in possession of the claimed invention (Remarks, page 6, last paragraph), Applicant is referred to more recent case law establishing that **possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features** (see, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord Ex Parte Kubin, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1). The full scope of the claims are not described because of lack of a complete or partial structure other than the core sequence of SEQ ID NOs: 2, 9, 10, 11 and/or 12.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 10, 11, 14, 15, 17, 20-22, and 26-28 **remain rejected** under 35 U.S.C. 103(a) as being unpatentable over Gozes et al., US Patent 6,613,740 (2 September 2003, priority to 7 February 1997),WO 98/35042 (published 13 August 1998), and Brenneman et al., (US PreGrant Publication US 20020111301, published 15 August 2002) (all previously cited of record in the Office Action of 6 July 2006), for the reasons of record and the reasons set forth herein.

The claims are drawn to a method of treating multiple sclerosis (MS) by administering a composition comprising an ADNF III polypeptide comprising the amino acid core sequence NAVPSIPQ (SEQ ID NO: 2), further comprising an ADNF polypeptide comprising the amino acid core sequence SALLRSIPA (SEQ ID NO: 1).

Applicant argues that the previous Office Action does not establish a prima facie case of obviousness in light of In re Rouffet, 47 USPQ2d 1453 and In re Dembiczak, 50 USPQ2d 1614 (1999) (Remarks, p. 8, second paragraph). Applicant argues that one of skill in the art would not have reasonably expected success in treating an autoimmune disease using an ADNF III polypeptide (Remarks, p. 8, third paragraph). Applicant argues that none of the cited references specifically teach or suggest the treatment of the species of multiple sclerosis (Remarks, p. 9, first paragraph). Applicant argues that the cited references disclose and demonstrate the prevention of neuronal cell death after administration of ADNF III proteins (Remarks, p. 9, second paragraph). Applicant argues that in contrast, using a mouse

model for multiple sclerosis, the specification provides evidence that the administration of ADNF III protein inhibits the proliferation of immune cells (references pages 31, lines 5-11 and claim 29 (now cancelled)) (Remarks, p. 9, second paragraph). Applicant argues that the cited references provide no teachings that would lead those of skill in the art to predict that administration of ADNF III would have an effect on immune cell proliferation and thus would be useful to treat autoimmune diseases, including multiple sclerosis (Remarks, p. 9, second paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

The instant case is clearly distinguished from the facts and holdings in both In re Rouffet, 47 USPQ2d 1453 (Fed. Cir. 1998) and In re Dembiczak, 50 USPQ2d 1614 (Fed Cir. 1999). First, in In re Rouffet, the Federal Circuit held that the predicate motivation to combine was missing because "a lofty level of skill alone does not suffice to supply a motivation to combine" (Id. at 1659). However, the instant rejection did not merely recite that "the level of skill in the art is high" as in In re Rouffet. Rather, the instant rejection specifically established that the level of skill of those in the art encompasses skills in the field of molecular biology relating to the treatment of autoimmune diseases. Further, the instant rejection established that at the time of the invention, there was a recognized problem or need in the art to treat multiple sclerosis; that there were a finite number of identified, predictable potential solutions to treat related neurological and autoimmune disorders using an ADNF polypeptide or active core sequence thereof; that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success because the '740 patent and WO 98/35042 teach the use of ADNF polypeptides and active core sequences thereof for neurological and autoimmune disorders and Brenneman et al., teach the administration of ADNF polypeptides to treat conditions related to increased neuronal cell death; and that a person of ordinary skill in the art at the time the invention was made would have reasonably know that the ADNF polypeptides and active core sites thereof would have useful in the treatment of neurological disorders, including autoimmune neurological disorders, and would also be useful in the treatment of multiple sclerosis (see Office Action of 11/27/2007, page 8). Additionally, the Office Action of 11/27/2007 specifically stated that "[i]t would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat MS in a subject by administering a therapeutically effective dose of an ADNF polypeptide or a peptide comprising the active core site thereof (NAVPSIPQ or SALLRSIPA) as taught by '740 patent and WO 98/35042. Treatment would have been predictable because the '740 patent and WO 98/35042 teach the administration ADNF peptides as therapeutics to treat neurodegenerative disorders" (Office Action of 11/27/2007, page 9, third paragraph). As such, the Office Action of 11/27/2007 is clearly distinguished from In re Rouffet. Moreover, the US

Supreme Court in KSR v. Teleflex, 550 US ___, 82 USPQ2d 1385 (30 April 2007), Specifically held that a suggestion or motivation to combine is only one factor that must be considered, and that the prior Federal Circuit teaching/suggestion/motivation (TSM) test is not a rigid test. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a known composition used to treat a specific disorder was obvious to try might show that it was obvious under 35 USC 103. Second, the holding of In re Dembiczak, insofar as it requires an absolute showing of the TSM test, has been overruled by the US Supreme Court in KSR v. Teleflex, 550 US ___, 82 USPQ2d 1385 (30 April 2007). In KSR v. Teleflex, a unanimous Supreme Court reminded the Court of Appeals for the Federal Circuit that Graham v. John Deere controls the obviousness inquiry and warned that a rigid application of the teaching/suggestion/motivation test as a litmus test for obviousness is inconsistent with the Graham framework.

With regard to Applicant's argument that one of skill in the art would not have reasonably expected success in treating an autoimmune disease using an ADNF III polypeptide (Remarks, p. 8, third paragraph), the cited art teaches methods of using ADNF III polypeptides in the treatment of the neuro-autoimmune diseases including Guillian-Barre syndrome. WO 98/35042 also teaches that those of skill in the art will appreciate that the list of neurodegenerative disorders is not exhaustive and that ADNF III polypeptides can be used to treat other neurological disorders (page 8, lines 16-18). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to treat MS in a subject by administering a therapeutically effective amount of an ADNF polypeptide or active core site thereof as taught by the '740 patent, WO 98/35042, and Brenneman et al., with a predictable expectation of success because the '740 patent and WO 98/35042 teach the administration ADNF peptides as therapeutics to treat neurodegenerative disorders, including Guillan-Barre syndrome, and Brenneman et al., teach the use of ADNF polypeptides to treat conditions related to increased neuronal cell death. As stated in the Office Action of 11/27/2007 and above, at the time of the invention, there was a recognized problem or need in the art to treat multiple sclerosis. There were a finite number of identified, predictable potential solutions to treat related neurological and autoimmune disorders using an ADNF polypeptide or active core sequence thereof. One of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success because the '740 patent and WO 98/35042 teach the use of ADNF polypeptides and active core sequences thereof for neurological and autoimmune disorders and Brenneman et al., teach the administration of ADNF polypeptides to treat conditions related to increased neuronal cell death. A person of ordinary skill in the art at the time the

invention was made would have reasonably know that the ADNF polypeptides and active core sites thereof would have useful in the treatment of neurological disorders, including autoimmune neurological disorders, and would also be useful in the treatment of multiple sclerosis.

With regard to Applicant's argument that the prior art did not appreciate the property of ADNF III polypeptides inhibiting the proliferation of immune cells is not relevant to the obviousness analysis. "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus, the claiming of a **new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable**. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."). Further, the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir.1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

8. Claims 12, 13, 18, and 19 **remain rejected** in addition to claims 1, 10, 11, 14, 15, 17, 20-22, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gozes et al., US Patent 6,613,740 (2 September 2003, priority to 7 February 1997), WO 98/35042 (published 13 August 1998), Brenneman et al., (US PreGrant Publication US 2002/001301 A1, published 15 August 2002), and Voet et al., (1995 Biochemistry, 2nd Ed., p. 67) and Goodman et al., (US Patent 4,587,046, 6 May 1986) (all previously cited of record in the Office Action of 6 July 2006), for the reasons of record and the reasons set forth herein.

Applicant argues that the previous Office Action does not establish a prima facie case of obviousness in light of In re Rouffet, 47 USPQ2d 1453 and In re Dembiczak, 50 USPQ2d 1614 (1999) (Remarks, p. 8, second paragraph). Applicant also argues that neither Voet et al., nor Goodman et al., provide teachings regarding treatment of any disease using ADNF III polypeptides including autoimmune diseases such as multiple sclerosis (Remarks, p. 9, third paragraph). Applicant argues that neither Voet et al., nor Goodman et al., can overcome the deficiencies of WO 98/35042 or Gozes et al. (Remarks, p 9, third paragraph). Applicant argues that this group of cited references fails to render predictable inhibition of immune cell proliferation by administration of ADNF III polypeptides. Applicant's arguments have been fully considered, but they are not persuasive.

Applicant's arguments regarding In re Rouffet and In re Dembiczak are responded to in detail above. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Voet et al., and Goodman et al., were cited for their teachings regarding D-amino acids.

With regard to Applicant's argument that one of skill in the art would not have reasonably expected success in treating an autoimmune disease using an ADNF III polypeptide (Remarks, p. 8, third paragraph), the cited art teaches methods of using ADNF III polypeptides in the treatment of the neuro-autoimmune diseases including Guillian-Barre syndrome. WO 98/35042 also teaches that those of skill in the art will appreciate that the list of neurodegenerative disorders is not exhaustive and that ADNF III polypeptides can be used to treat other neurological disorders (page 8, lines 16-18). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to treat MS in a subject by administering a therapeutically effective amount of an ADNF polypeptide or active core site thereof as taught by the '740 patent, WO 98/35042, and Brenneman et al., with a predictable expectation of success because the '740 patent and WO 98/35042 teach the administration ADNF

peptides as therapeutics to treat neurodegenerative disorders, including Guillan-Barre syndrome, and Brenneman et al., teach the use of ADNF polypeptides to treat conditions related to increased neuronal cell death. As stated in the Office Action of 11/27/2007 and above, at the time of the invention, there was a recognized problem or need in the art to treat multiple sclerosis. There were a finite number of identified, predictable potential solutions to treat related neurological and autoimmune disorders using an ADNF polypeptide or active core sequence thereof. One of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success because the '740 patent and WO 98/35042 teach the use of ADNF polypeptides and active core sequences thereof for neurological and autoimmune disorders and Brenneman et al., teach the administration of ADNF polypeptides to treat conditions related to increased neuronal cell death. A person of ordinary skill in the art at the time the invention was made would have also reasonably known that L-amino acids could readily be substituted with D-amino acids by well-known means and with routine experimentation. One of skill in the art would have also known that such substitutions are routine and increase the stability of peptides.

As explained above, Applicant's argument that the prior art did not appreciate the property of ADNF III polypeptides inhibiting the proliferation of immune cells is not relevant to the obviousness analysis. "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus, the claiming of a **new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable**. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d

1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."). Further, the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir.1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

New Claim Rejections - Based on New Claim Amendments in Copending Case

Provisional Obviousness-Type Double Patenting Rejection

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 11, 14, 17, 20, and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 23 of copending Application

No. 11/388,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because newly amended claims 1 and 23 of the '634 application disclose a method for treating peripheral neurotoxicity in a subject comprising administering a therapeutically effective amount of an ADNF III polypeptide comprising NAVSIPQ (SEQ ID NO: 2) (claim 1 subpart b) (compare instant claims 1, 11, 14) or a mixture of an ADNF III polypeptide comprising NAVSIPQ (SEQ ID NO: 2) and an ADNF I polypeptide comprising SALLRSIPA (SEQ ID NO: 1) (claim1 subpart c) (compare instant claims 1, 17, 20, and 21), wherein said peripheral neurotoxicity is a consequence of treatment with one or more chemical agents; wherein said one or more chemical agent is selected among chemical agents for multiple sclerosis (claim 23) (compare instant claim 1). The instant claims are broadly encompass the administration of a composition comprising an ADNF III polypeptide or an ADNF III and ANDN I polypeptide in the treatment of multiple sclerosis.

It is noted that although the instant claims have not been amended, claims 1 and 23 in 11/388,634 were amended on 15 February 2008 and render the instantly claimed subject matter obvious over the amended claims in 11/388,634. The instant application and the '634 application have at least one inventor in common.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMW/
AU 1647

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646